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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. _____

To authorize the Food and Drug Administration to require manufacturers of infant formula to warn about a discontinuance or interruption in the production of infant formula, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. JOHNSON of South Dakota introduced the following bill; which was referred to the Committee on _____

A BILL

To authorize the Food and Drug Administration to require manufacturers of infant formula to warn about a discontinuance or interruption in the production of infant formula, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Formula Shortage Re-
5 porting Act of 2022”.

1 **SEC. 2. REQUIREMENT TO WARN ABOUT DISCONTINUANCE**
2 **OR INTERRUPTION IN THE PRODUCTION OF**
3 **INFANT FORMULA.**

4 (a) IN GENERAL.—Section 412 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 350a) is amended by
6 adding at the end the following:

7 “(j)(1) A manufacturer of infant formula shall notify
8 the Secretary, in accordance with paragraph (2), of a per-
9 manent discontinuance in the manufacture of the infant
10 formula or an interruption of the manufacture of the in-
11 fant formula that is likely to lead to a meaningful disrup-
12 tion in the supply of that infant formula in the United
13 States, or a permanent discontinuance in the manufacture
14 of an infant formula component or an interruption in the
15 manufacture of an infant formula component that is likely
16 to lead to a meaningful disruption in the supply of the
17 infant formula component, and the reasons for such dis-
18 continuance or interruption. Notification under this sub-
19 section shall include disclosure of—

20 “(A) reasons for the discontinuance or interrup-
21 tion;

22 “(B) if an infant formula component is a rea-
23 son for, or a risk factor in, such discontinuance or
24 interruption, the source of the infant formula com-
25 ponent and any alternative sources for the infant
26 formula component known by the manufacturer;

1 “(C) whether any associated device used for
2 preparation or administration included in the infant
3 formula is a reason for, or a risk factor in, such dis-
4 continuance or interruption;

5 “(D) in the case of an interruption, the ex-
6 pected duration of the interruption; and

7 “(E) such other information as the Secretary
8 may require.

9 “(2) A notice required under paragraph (1) shall be
10 submitted to the Secretary—

11 “(A) at least 72 hours prior to the date of the
12 discontinuance or interruption; or

13 “(B) if compliance with subparagraph (A) is
14 not possible, as soon as practicable.

15 “(3) If a manufacturer of infant formula determines
16 that compliance with paragraph (2)(A) is not possible, the
17 manufacturer shall submit such determination in writing
18 to the Secretary and the justification for such determina-
19 tion.

20 “(4) To the maximum extent practicable, the Sec-
21 retary shall distribute to health care providers who treat
22 pregnant women and children under the age of 2, and
23 make publicly available on the website of the Food and
24 Drug Administration, information on the discontinuance

1 or interruption of the manufacture of the infant formula
2 described in paragraph (1).

3 “(5) Nothing in this subsection shall be construed as
4 authorizing the Secretary to disclose any information that
5 is a trade secret or confidential information subject to sec-
6 tion 552(b)(4) of title 5, United States Code, or section
7 1905 of title 18, United States Code.

8 “(6) The Secretary shall find a manufacturer of in-
9 fant formula to be in violation of this section if—

10 “(A) the Secretary determines that—

11 “(i) the manufacturer has failed to submit
12 the notice required by paragraph (2) and the
13 determination and justification required by
14 paragraph (3); or

15 “(ii) the determination and justification
16 submitted by the manufacturer are insufficient;

17 “(B) the Secretary issues a letter to such man-
18 ufacturer—

19 “(i) informing such manufacturer of such
20 failure or insufficiency; and

21 “(ii) giving such manufacturer a period of
22 not more than 30 calendar days to correct such
23 failure or insufficiency; and

1 “(C) the Secretary determines such manufac-
2 turer has failed to correct such failure or insuffi-
3 ciency by the end of such period

4 “(7) For purposes of this subsection—

5 “(A) the term ‘infant formula component’
6 means a raw or in-process material, ingredient, con-
7 tainer, or closure used in the manufacturing or proc-
8 essing of infant formula;

9 “(B) the term ‘infant formula shortage’ or
10 ‘shortage’, with respect to an infant formula, means
11 a period of time when the demand or projected de-
12 mand for the infant formula within the United
13 States exceeds the supply of the infant formula; and

14 “(C) the term ‘meaningful disruption’—

15 “(i) means a change in production that is
16 reasonably likely to lead to a reduction in the
17 supply of an infant formula by a manufacturer
18 that is more than negligible and affects the
19 ability of the manufacturer to fill orders or
20 meet expected demand for its product; and

21 “(ii) does not include interruptions in man-
22 ufacturing due to matters such as routine main-
23 tenance or insignificant changes in manufac-
24 turing so long as the manufacturer expects to
25 resume operations in a short period of time.”.

1 (b) PROHIBITED ACT.—Section 301 of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
3 ed by adding at the end the following:

4 “(fff) The failure by a manufacturer of infant for-
5 mula, with respect to a notice of discontinuance or inter-
6 ruption, to make a correction as required by section
7 412(j)(6)(C).”.